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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,631	03/01/2002	Stephan Jaeger	1803-335-999	3750

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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,631	STEPHAN JAEGER	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-14,20-22,24-28 and 30-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-14,20-22,24-28 and 30-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed December 6, 2004 is acknowledged and has been entered. Claims 1-8, 15-19, 23, and 29 have been canceled. Claims 9 and 13 have been canceled. Claims 34-49 have been added. Claims 9-14, 20-22, 24-28 and 30-49 are pending in the instant application.

All of the amendments and arguments have been thoroughly reviewed and considered but are deemed moot in view of the new grounds of rejections. The indication of allowable subject matter of claims 23 and 29 have been withdrawn in view of the new grounds of rejection in this Office Action. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Ground(s) of Rejections

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 9-12, 21, 22, 24, 25 and 34-36, 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gagnor et al (Nucleic acids Research, Vol. 17, No. 13, pages 5701-5114) in view of Mullis (Us 4683202 A, July 1987). Regarding claims 9, 22, 34 and 40, Gagnor et al teach a composition comprising a target nucleic acid and a control

nucleic acid (ps-β-I and ps-α-II), wherein said control nucleic acid comprises at least one contiguous sequence of at least 8 (clm 9) or at least 10 (clm 22) nucleotides in length essentially parallel complementary to said target nucleic acid region (see Figure 1, page 5108 and page 5110, first paragraph, under "Results", lines 1-10). Gragnor et al differs from the instant invention in that the reference does not teach wherein the composition comprises a thermostable polymerase. However, Gragnor et al do teach wherein the composition comprises primers/probes and comprises a primer and/or probe binding site for use in a RT-PCR reaction and hybridization reaction (page 5109 to 5110, section entitled "Materials and Methods").

Mullis et al teach composition comprising a thermostable polymerase, a target nucleic acid, a control nucleic acid and primers for use in amplification and hybridization reactions. Mullis teach wherein the thermostable polymerase is added to the composition as an inducing agent and is useful because the thermostable polymerase will operate at an elevated temperature in an amplification reaction (col. 2, lines 37-col. 3, line 25 and col. 8, line 66 to col. 9, line 3). Mullis further teaches that the amplification reaction comprising the use of the composition described therein is useful not only for producing large amounts of an existing nucleic acid of completely specified sequence, but also for producing nucleic acid sequences which are known to exist but are not completely specified (col. 2, lines 19-25). Mullis additionally teach that the amplification process may be useful for diagnosing the presence of a specific nucleic acid sequence suspected of being in a sample, thus indicative of a pathological state or disease (col. 14, lines 66-68 to col. 15, lines 1-37).

Therefore, in view of the foregoing, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have modified the composition as taught by Gagnor et al to encompass a thermostable polymerase and additional primers for use of the composition in polymerase chain amplification reaction as taught by Mullis. One of ordinary skill in the art at the time of the claimed invention would have been further motivated to have modified the composition as taught by Gagnor for used of the composition in amplification reactions for the advantages of producing large amounts of an existing nucleic acid of a completely specified sequence or for producing a sequence which is known to exist but is not completely specified or for the benefits of diagnosing a pathological state or disease as suggested by Mullis.

Regarding claims 10-12, and 35-36, Gagnor et al teach the composition of claim 9, wherein said target nucleic acid comprises a primer binding site or a probe binding site and said control nucleic acid comprises a sequence that is parallel complementary to the primer binding site or probe binding site of the target nucleic acid (Figure 1, page 5108; page 5110, first paragraph, under "Results", lines 1-10 and page 5112, lines 3-7).

Regarding claim 21 and 38, Gagnor et al teach the composition of claim 9, wherein the target nucleic acid is an RNA molecule (Figure 1 and page 5110, first paragraph, under "Results", lines 1-10).

Regarding claim 24, 25 and 41, Gagnor et al teach the composition of claim 10, further comprising a primer or probe (aps-β-I and aps-α-II) that binds to the primer-binding site or the probe-binding site (Figure 1, page 5108).

5. Claims 13, 14, 27, 28, 30, 31-33, 42, 44-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gagnor et al in view of Mullis as previously applied above and further in view of Ahern, H. (The Scientist, vol. 9, No. 15, pages 20-24, July 1995). Regarding claims 13, 28, 42, 45, and 46, Gagnor et al in view of Mullis et al teach the composition as previously described above. Gagnor et al in view of Mullis et al differs from the instant invention in that the reference does not expressly teach the composition in the form of kit.

In a scientific article, Ahern teaches the advantages of a kit and provides motivation for combining reagents in the form of a kit. Ahern teaches that a kit provides convenience, time management and ease of practicing to the investigator (page 23, second-forth paragraphs). Therefore, in view of the teaching of Ahern, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have combined the composition as taught by Gagnor et al in view of Mullis et al in the form of a kit for the obvious benefits of convenience, time management and ease of practicing to the investigator as suggested by Ahern.

Regarding claims 14, 30, 32, 47, 48, Gagnor et al teach the composition of claims 13 and 42, wherein said target nucleic acid comprises a primer binding site or a probe binding site and said control nucleic acid comprises a sequence that is parallel complementary to the primer binding site or probe binding site of the target nucleic acid (Figure 1, page 5108; page 5110, first paragraph, under "Results", lines 1-10 and page 5112, lines 3-7).

Regarding claims 27 and 44, Gagnor et al teach the composition of claims 13 and 42 wherein the target nucleic acid is an RNA molecule (Figure 1 and page 5110, first paragraph, under "Results", lines 1-10).

Regarding claims 31, 33, and 49, Gagnor et al teach the composition of claims 13 and 48, further comprising a primer or probe (aps-β-I and aps-α-II) that binds to the primer-binding site or the probe-binding site (Figure 1, page 5108).

6. Claims 9, 20 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolli et al. (Nucleic acids Research, vol. 24, No. 23, pages 4665-4672) in view of Mullis et al (US 4683202 A). Regarding claims 9, 20 and 37, Bolli et al teach a composition comprising a target nucleic acid and a control nucleic acid, wherein said control nucleic acid comprises at least one contiguous sequence of at least 8 nucleotides in length essentially parallel complementary to said target nucleic acid region or to the complementary strand of said target nucleic acid region. Bolli et al further teach wherein said target nucleic acid is DNA (see Table 2 at C). Bolli et al differs from the instant invention in that the reference does not teach a thermostable polymerase and primer for amplification reaction.

Mullis et al teach composition comprising a thermostable polymerase, a target nucleic acid, a control nucleic acid and primers for use in amplification and hybridization reactions.. Mullis teach wherein the thermostable polymerase is added to the composition as an inducing agent and is useful because the thermostable polymerase will operate at an elevated temperature in an amplification reaction (col. 2, lines 37-col. 3, line 25 and col. 8, line 66 to col. 9, line 3). Mullis further teaches that the amplification reaction

comprising the use of the composition described therein is useful not only for producing large amounts of an existing nucleic acid of completely specified sequence, but also for producing nucleic acid sequences which are known to exist but are not completely specified (col. 2, lines 19-25). Mullis additionally teach that the amplification process may be useful for diagnosing the presence of a specific nucleic acid sequence suspected of being in a sample, thus indicative of a pathological state or disease (col. 14, lines 66-68 to col. 15, lines 1-37).

Therefore, in view of the foregoing, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have modified the composition as taught by Bolli et al to encompass a thermostable polymerase and additional primers for use of the composition in polymerase chain amplification reaction as taught by Mullis. One of ordinary skill in the art at the time of the claimed invention would have been further motivated to have modified the composition as taught by Bolli et al for used of the composition in amplification reactions for the advantages of producing large amounts of an existing nucleic acid of a completely specified sequence or for producing a sequence which is known to exist but is not completely specified or for the benefits of diagnosing a pathological state or disease as suggested by Mullis.

7. Claims 13, 26 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolli et al. in view of Mullis et al as previously applied above and further in view of Ahern, H (The Scientist, Vol. 9, No. 15, pages 20-24, July 1995). Regarding claims 13, 26 and 43, Bolli et al in view of Mullis et al teach a composition as previously discussed

above. Bolli et al in view of Mullis et al differ from the instant invention in that the reference does not teach the composition in the form of a kit.

In a scientific article, Ahern teaches the advantages of a kit and provides motivation for combining reagents in the form of a kit. Ahern teaches that a kit provides convenience, time management and ease of practicing to the investigator (page 23, second-forth paragraphs). Therefore, in view of the teaching of Ahern, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have combined the composition as taught by Bolli et al in view of Mullis et al in the form of a kit for the obvious benefits of convenience, time management and ease of practicing to the investigator as suggested by Ahern.

Conclusion

8. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

CYNTHIA WILDER
PATENT EXAMINER
3/6/2005